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APPLICATION FOR UNITED STATES LETTERS PATENT

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Title: APPETITE SUPPRESSANT

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SPECIFICATION

APPETITE SUPPRESSANT

This application claims priority to U.S. Provisional Patent Application Serial No. 60/510,857, filed October 14, 2003, and is a continuation-in-part of U.S. Patent Application Serial No. 10/744,269, filed December 22, 2003.

FIELD OF THE INVENTION

The invention is directed to a method of appetite suppression.

BACKGROUND

5 A composition of wheat bran, wheat, molasses, corn-derived maltodextrin, and natural coffee flavor is commercially available under the trademark POSTUM®. Product descriptions of POSTUM® state that the

wheat has been roasted and mixed with a small amount of pure molasses. This composition has been used as a cereal food since the early twentieth century, and has been used as a coffee substitute beverage since the mid-twentieth century.

- 5 The invention discloses other methods of using this product apart from its nutritive and/or taste value.

SUMMARY OF THE INVENTION

- A method of suppressing appetite in an individual by ingesting an appetite-suppressant amount of wheat bran, wheat,
10 molasses, and corn-derived maltodextrin at an interval prior to or with at least one meal to suppress appetite and thereby facilitate reduction of total caloric intake during the meal. The components may be contained in one or more biocompatible inert capsules.

- Another embodiment is a method of suppressing appetite in
15 an individual by ingesting an appetite-suppressant amount of a grain such as wheat, corn, rye, rice, oats, or barley, that has been roasted for an interval sufficient to caramelize the grain, the ingestion with or at an interval prior to a meal to suppress appetite and thereby facilitate reduction of total caloric intake during the meal. The grains may be contained in one
20 or more biocompatible inert capsules.

 Another embodiment is a method of suppressing appetite in an individual by ingesting wheat bran, wheat, molasses and corn-derived maltodextrin with or at an interval prior to at least one meal to suppress appetite without the use of non-natural components, botanicals, or herbs.

Another embodiment is a kit comprising a composition of at least one of wheat bran, wheat, molasses and corn-derived maltodextrin, and instructions for consuming an appetite-suppressant amount of the composition with or at an interval prior to at least one meal to suppress
5 hunger and thereby facilitate reduction of total caloric intake during the meal. The kit may contain the composition in oral dosage forms such as capsules. The instructions may contain suggested or recommended dosages.

Another embodiment is a method of suppressing appetite in
10 an individual by ingesting a foodstuff containing an appetite-suppressant amount of roasted wheat bran at an interval prior to or with at least one meal to suppress appetite and thereby facilitate reduction of total caloric intake during the meal. The foodstuff can also contain one or more of wheat, molasses, and corn-derived maltodextrin.

15 Another embodiment is a method of suppressing appetite in an individual by ingesting a beverage containing at least about one-half teaspoon of a composition comprising, in decreasing order, wheat bran, wheat, molasses, corn-derived maltodextrin, and natural coffee flavor, the composition dissolved in a liquid, at an interval prior to or with at least one
20 meal to suppress appetite.

Another embodiment is a method of suppressing appetite in an individual by ingesting a beverage comprising an appetite-suppressant amount of at least one of wheat bran, wheat, molasses, corn-derived

maltodextrin, and natural coffee flavor, the composition dissolved in a liquid, at an interval prior to or with at least one meal to suppress appetite.

The use of a mixture of roasted wheat bran that also contains wheat, molasses, corn-derived maltodextrin, and natural coffee
5 flavor, commercially available as POSTUM®, for appetite suppression and/or weight reduction, is disclosed. POSTUM® is a coffee substitute and is formulated as a powder or crystals. It is conventionally prepared by dissolving in boiling or hot water, as one would prepare instant coffee. It may also be consumed in a non-heated or cold form after it is dissolved, or
10 may be consumed as an ingredient in a food product. It may also be consumed in a oral dosage form of the type used for dietary supplements, such as a capsule, gelcap, etc.

In one embodiment, instructions are provided to consume POSTUM® either encapsulated, as a beverage, or as a food or food
15 supplement, before eating a meal (for example, up to one to two hours prior to eating) to suppress appetite. In another embodiment, instructions are provided to consume POSTUM® as a beverage during a meal to suppress appetite. Consumption of POSTUM® suppresses hunger and thereby facilitates reduction of total caloric intake during the meal, which
20 can result in weight reduction.

In another embodiment, the invention also includes consuming a product containing wheat bran, wheat, corn, rye, oats, barley, or another grain, that has been roasted to the point of caramelization. When the product is formulated as a beverage, an individual drinks a cup

of this beverage as previously described to suppress appetite. When the product is formulated in a solid food, an individual consumes a serving of the food to suppress appetite. When the product is formulated in an oral dosage form, an individual consumes one or more capsules, tablets, etc.

5 as previously described, to suppress appetite.

POSTUM® is made from wheat and other natural components. There are no herbs, botanicals, or other synthetic components that may be harmful when consumed. There are no stimulants, such as caffeine. Thus, the inventive method of suppressing
10 appetite and/or reducing weight is as safe as consuming POSTUM®, which has been available for over one hundred years. In alternative embodiments, dietary supplements may be included, and/or a laxative may be included. Other grain-based components that may be formulated into beverages, such as CAFIX® and PERO®, are also included within the
15 scope of the invention.

These and other advantages will be apparent in light of the following drawing and detailed description.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a histogram showing weight loss of individuals
20 practicing the inventive method.

DETAILED DESCRIPTION

A method of desirably suppressing or reducing appetite is disclosed. In one embodiment, the invention includes consumption for appetite suppression of a natural coffee flavored foodstuff containing the

following ingredients, either individually or collectively: wheat bran, wheat, molasses, corn-derived maltodextrin, where the grain may be roasted. In another embodiment, the invention includes consumption of a foodstuff containing an appetite-suppressant amount of wheat bran, either prior to a meal or concomitantly with a meal, to result in desirable appetite suppression. In another embodiment, the invention includes consumption for appetite suppression of a foodstuff containing a mixture of the following ingredients listed in relative decreasing order: wheat bran, wheat, molasses, corn-derived maltodextrin, and natural coffee flavor, commercially available as POSTUM®, prior to or with at least one meal to result in desirable appetite suppression. In another embodiment, the invention includes ingestion of an oral dosage form of the following ingredients, either individually or collectively: wheat bran, wheat, molasses, corn-derived maltodextrin, where the grain may be roasted. In another embodiment, the invention includes consumption of one or more oral dosage form(s) containing collectively an appetite-suppressant amount of wheat bran, either prior to a meal or concomitantly with a meal, to result in desirable appetite suppression. In another embodiment, the invention includes consumption for appetite suppression of one or more of an oral dosage form containing a mixture of the following ingredients listed in relative decreasing order: wheat bran, wheat, molasses, corn-derived maltodextrin, and natural coffee flavor, commercially available as POSTUM®.

A foodstuff is defined herein as a liquid (for example, a hot beverage, a shake, a smoothie, etc.), a solid (for example, snack bars, etc.), a semi-solid (for example, sorbets, yogurts, etc.). The instruction may include foodstuff consumption at intervals throughout the day, or as a
5 beverage with the meal.

Biocompatible vehicles that may be used in formulating the appetite suppressant in an oral dosage form are commercially available. These include two piece capsules available from Capsugel® (Morris Plains NJ). The capsule has a liquid gelatin consistency with both the cap
10 and body made from pharmaceutical grade gelatin forming gelatin shell layers. Soft capsules are familiar to consumers as vehicles for many types of prescription pharmaceuticals, over the counter pharmaceuticals, and dietary, health and beauty supplements. Color combinations may be selected to suit the appetite suppressant properties, consumer preference,
15 etc. In an alternative embodiment, a high gloss, taste-free gelatin coating may encase a caplet core; these are available from Capsugel® as Press-Fit® Gelcaps.

Gelatin capsules may be selected based upon fill amounts. For example, about three grams of the appetite suppressant composition,
20 such as POSTUM®, may be contained in a Torpac® (Fairfield NJ) one-eighth ounce size 13 capsule, or two or three gelatin caps –000- (each capsule containing an average of 1300 mg) or four to five gelatin caps –00- (each containing an average of 650 mg), or eight to nine gelatin caps –0- (each containing an average of 324 mg), all available from Herb

Cupboard (Elk Grove CA). Kosher capsules made from carbohydrate gum derived from vegetable cellulose, free from animal by-products, are available as Vegicaps® with average fills of 325 mg and 650 mg (Herb Cupboard), and may be dosed as previously described for gelatin caps.

- 5 Soft gelatin capsules are also available from Euro Caps Limited (Tredegar, Gwent UK), with the shell of bovine, porcine, or fish gelatin, and containing as excipients soya lecithin, soya bean oil, colloidal silicon dioxide, vegetable fat, and beeswax. Such oral dosage forms are soluble *in vivo*, biodegradable, non-toxic, and of natural protein origin. Other oral dosage
- 10 forms and methods for preparing oral dosage forms may be used and are known to one skilled in the art.

- A corollary effect of appetite suppression is weight reduction. Following weight loss, it is frequently desirable to maintain the reduced weight. In one embodiment, the invention also includes an instruction to
- 15 consume a foodstuff or oral dosage form containing an appetite-suppressant amount of wheat bran, either prior to a meal or concomitantly with a meal, to result in weight reduction and/or to maintain a desirable weight. In another embodiment, the invention also includes an instruction to consume a foodstuff or oral dosage form containing, in relative
- 20 decreasing order, a mixture of wheat bran, wheat, molasses, and corn-derived maltodextrin, commercially available as POSTUM®, at intervals throughout the day prior to eating a meal or with the meal to result in desirable weight reduction and/or to maintain a desirable weight. In another embodiment, the invention also includes an instruction to

consume a foodstuff or oral dosage form containing at least one of wheat bran, wheat, molasses, and corn-derived maltodextrin prior to a meal or with the meal to result in weight reduction and/or to maintain a desirable weight.

5 POSTUM® is available commercially from Kraft Foods, Rye Brook NY and is sold in supermarkets. The label lists the ingredients as wheat bran, wheat, molasses, maltodextrin (from corn), and natural coffee flavor. The ingredients are listed in decreasing order, such that quantitatively the main ingredient is wheat bran.

10 Wheat bran is the rough outer covering of a wheat kernel, commonly known as a wheat berry. It adds flavor and fiber to baked goods. While not bound by a specific theory, bran is a known bulking agent and may account for a substantial degree of the appetite suppressant effects by increasing the sensation of satiety or fullness. This
15 sensation may additionally or alternatively result from increasing the bulk in the stomach and upper digestive tract, and hence may actually increase the mass and/or volume of the stomach contents.

Wheat, molasses, maltodextrin (from corn), and natural coffee flavor may also account for and/or contribute to appetite-
20 suppressant/weight reduction effects. Wheat flour results from processing the wheat endosperm, the majority of the wheat kernel or wheat berry, and containing starch, protein, niacin and iron. Molasses is the remaining brown-black liquid when juice is squeezed from sugar cane and sugar beets and boiled to a syrupy mixture from which sugar crystals are

extracted. It is a sweetener and flavorant. Maltodextrin is also a sweetener and flavorant. It is a mixture of glucose, maltose, oligosaccharides, and polysaccharides obtained by partial hydrolysis of starch, and therefore also contains fiber. Natural coffee flavor is expected to provide flavorant properties (taste and/or aroma), and is not expected to contribute to the appetite suppressant effect.

The appetite suppressant amount of an ingredient will vary depending upon the properties of the ingredient, as known to one skilled in the art. As one example, wheat bran, which provides fiber, would be expected to have a greater appetite suppressant effect than wheat flour. As another example, wheat bran would be expected to contain a greater amount of fiber than maltodextrin, and thus would be expected to contribute more to an appetite suppressant effect than maltodextrin.

The ingredients may be present, individually or in combination, in various concentrations. The concentration of wheat bran may range from about 1%^{w/w} to about 20%^{w/w}. In one embodiment, the concentration of wheat bran ranges from about 5%^{w/w} to about 10%^{w/w}. The concentration of wheat may range from about 5%^{w/w} to about 15%^{w/w}. In one embodiment, the concentration of wheat ranges from about 3%^{w/w} to about 5%^{w/w}. The concentration of molasses may range from about 0.2%^{w/w} to about 10%^{w/w}. In one embodiment, the concentration of molasses ranges from about 2%^{w/w} to about 5%^{w/w}. The concentration of maltodextrin may range from about 0.1%^{w/w} to about 5%^{w/w}. In one embodiment, the concentration of maltodextrin ranges from about 0.5%^{w/w}

to about 2% ^{w/w}. In one embodiment, up to about 35% of the composition is wheat and wheat bran. The grains may be roasted or unroasted.

If not used in an oral dosage form as previously described, POSTUM® is prepared according to package directions, typically, at least
5 one teaspoonful, which is indicated on the label as about three grams, in about eight ounces of boiling water, and stirred until dissolved. It may also be prepared as one ingredient in solid foods such as chewy bars or semi-solid foods such as sorbet as listed on the manufacturer's web site (kraftfoods.com), or may be added to solid or semi-solid foods (for
10 example, yogurt). The amount of POSTUM® may be increased, for example, one-and-one-half teaspoons, two teaspoonfuls, two-and-one-half teaspoonfuls, etc. The exact amount of POSTUM® may be determined by palatability, dissolvability in the volume of water typically contained in a coffee cup or mug, etc. While less than one teaspoonful of POSTUM®
15 may be consumed in a serving, a lesser degree or extent of appetite suppression and/or rate of weight reduction may result. Flavoring agents such as milk, cream, non-dairy creamer, sugar, a sugar substitute, vanilla, or other flavorants may be added. The beverage or food is then consumed. If the beverage is hot or warm, it may be consumed
20 incrementally in small sips, as one would consume hot or warm coffee. If the beverage is cold or chilled, it may be consumed in larger portions.

In one embodiment of the invention, the beverage, food, or oral dosage form is consumed prior to meals such that an appetite suppressant effect is achieved by the time the individual eats the meal.

Consumption may occur anytime before a meal, for example, up to about two hours prior to eating, up to about one hour prior to eating, or immediately prior to eating. If orally ingested in a dosage form (for example, one or more gelcaps), the time for capsule dissolution can be considered in the dose interval. It may be consumed before each regular meal (that is, before breakfast, before lunch, and before dinner), or it may be consumed at specified meals (for example, before dinner only, etc.). In another embodiment, the beverage or food is consumed with the meal. The regimen may alternate these embodiments, for example, POSTUM® may be consumed prior to one meal, but concomitantly with another meal.

The individual experiences a feeling of satiety and thus is able to achieve reduced total caloric intake at each meal without feeling hungry. In one individual, drinking one cup of POSTUM® prior to each of breakfast, lunch, and dinner, reduced appetite to the extent that a weight loss of six pounds was achieved over a two-month period without a corresponding feeling of hunger and desire for food.

Other grain-based compositions that can be formulated into beverages are also included within the scope of the invention. As one example, CAFIX® (InterNatural Foods, Paramus NJ) powder is a caffeine free powder blend of malted barley, barley, chicory, rye, and beet roots. According to label directions, it may be prepared by stirring one teaspoon (indicated as 1.5 g) or more into six ounces of boiling water or milk. CAFIX® crystals is a caffeine free blend of roasted barley, rye, chicory, and beet roots. According to label directions, a serving size is one

teaspoon (indicated as 2 g). As another example, PERO® (Nestle, Vevey, Switzerland) is a caffeine-free blend of malted barley, barley, chicory, and rye.

In one embodiment, an oral dosage form of the appetite suppressant may further contain a laxative. Laxatives which may be formulated with the appetite suppressant, for example, in mixture or admixture, include but are not limited to psyllium powder, cellulose derivatives, the edible portion of the *Carum carvi* plant, dioctyl sulfosuccinate, and/or sennosides (senna extracts). The amount of laxative varies depending upon the type; exemplary amounts are provided in U.S. Patent Nos. 6,361,799; 5,811,125; 5,710,183; 5,516,524; 5,514,663; and 5,073,370, each of which are incorporated by reference herein in its entirety. For example, the amount of sennoside added to POSTUM® provided in an oral dosage form (that is, about three grams of POSTUM®) ranges from about 1 mg to about 100 mg per gram of POSTUM®. In another embodiment, the amount of sennoside is from about 1 mg to 25 mg per three grams of POSTUM®.

In one embodiment, the composition may further contain dietary supplements. These include but are not limited to minerals, vitamins, nutrients, and/or nutraceuticals, such as vitamins (for example, A, D, E, K, B series, C, folic acid, biotin, pantothenic acid), lipids (for example, cod liver oil, wheatgerm oil, starflower oil, lecithin, linolenic acid, linoleic acid, fish oils), garlic extracts or products, glucosamine, and

minerals (for example, calcium, phosphorous, magnesium, manganese, molybdenum, zinc, selenium, copper, chromium, iodine, and/or iron).

The following data were obtained from a group of twenty-one adults consuming POSTUM® according to the inventive method. More specifically, ten men and eleven women were asked to prepare and consume POSTUM® as a hot beverage before or during at least one of breakfast, lunch, or dinner. They were instructed to consume meals that did not qualitatively differ from their meals prior to the study; that is, the content of their meals did not change. They were also instructed to continue any on-going exercise regimen, but not to initiate a new exercise regimen.

None of the twenty-one participants was able to drink POSTUM® before each meal; that is, before breakfast, before lunch, and before dinner. However, all participants reported that they consumed the beverage before at least 50% of their meals. The compliance range was between 50% and 80% of the meals for all participants.

The data are as follows.

	Participant	Weight Change (pounds)	Participant	Weight Change (pounds)
20	Male 1	-5	Female 1	-2.6
	Male 2	-4	Female 2	-5
	Male 3	0	Female 3	+1.8
	Male 4	-5	Female 4	+0.5
25	Male 5	-4	Female 5	+3
	Male 6	-4	Female 6	-2
	Male 7	-3	Female 7	+0.5
	Male 8	-2	Female 8	+6
	Male 9	0	Female 9	0
30	Male 10	-3	Female 10	0
			Female 11	-2

Comparative results are shown in FIG. 1. As illustrated in FIG. 1, none of the male participants gained weight. Eight of the ten male participants lost between two pounds and five pounds over the four-week period. The mean weight change for males over the four-week period was a weight
5 loss of three pounds.

In contrast, five of the female participants gained weight. Four of the females lost weight during the four-week period, and two of the females maintained their weight. Of the five females who gained weight, two of these gained only half a pound, one gained almost two pounds, one
10 gained three pounds, and the other gained six pounds. The mean weight change for females over the four-week period was a weight gain of 0.2 pounds.

The weight loss results for male participants compared to female participants was statistically significant ($p \leq 0.05$). Specifically, the
15 male participants had a mean weight change of -3.0 pounds \pm -0.58 pound. The female participants had a mean weight change of +0.018 pound \pm 0.897 pound. Thus the weight loss experienced by men was significant at the 95% confidence interval.

All of the participants, both male and female, reported ease
20 of compliance with the study regimen. All of the participants who lost weight (eight men and four women) decided to continue with the regimen on their own. All of these individuals reported that they are pleased with their "effortless" loss of weight.

While not wishing to be bound by any theory, the male and female participants who reported no weight loss, or reported a weight gain, were questioned about their eating habits between meals. All of the women who gained weight reported snacking between meals, and one of
5 the two men who did not experience a weight change also reported snacking between meals.

Additionally, all participants without exception (that is, both men and women, participants who lost weight, those who maintained their weight, and those that gained weight) reported improvements in the quality
10 of sleep. Specifically, the participants reported that they slept more soundly, woke less frequently during sleep, and felt better rested during the day. While not wishing to be bound by any theory, the improved quality of sleep may be due to the feeling of satiety provided by consumption of POSTUM®. It is possible that waking during sleep or less
15 sound sleep may be due to hunger signals, which consumption of POSTUM® may reduce or prevent.

It will be appreciated that the components or ingredients in POSTUM®, that is, grains and grain products, are natural. POSTUM® also lacks the stimulant caffeine that is found in coffee. Additionally, wheat
20 bran, wheat, molasses, and corn-derived maltodextrin are well-characterized and known components. The method thus achieves appetite suppression and/or weight reduction and/or weight maintenance with natural components whose properties are well known. That is, it achieves these effects without the use of botanicals, herbs, nutraceuticals,

and other components that, while found in nature, may have effects that are potentially or actually harmful. Thus, the invention provides a method of appetite suppression and/or weight reduction that is achieved without either synthetic compounds, or without compounds that may have

5 potentially harmful effects due to uncharacterized components or interactions.

In another embodiment, consumption in liquid or solid form of roasted grain may be used as an appetite suppressant, and instructions for consumption to achieve weight reduction may be provided. Grains,

10 such as wheat, corn, rice, rye, barley, oats, malt, etc., undergo a caramelization process when they are roasted due to slow heating of the natural sugars in these grains. Caramelization is a transformational process of sugar(s) in the foodstuff brought about by frictional heating of the foodstuff at a sufficiently rapid rate so that an exothermic reaction

15 degrades the sugar(s). Glycosidic bonds degrade, followed by condensation and the formation of water, then caramelization begins. The heating rate is controlled to avoid burning the foodstuff by too rapid heating, and to avoid sweating the foodstuff by too slow heating. Once caramelization begins, the foodstuff must not exotherm, or lose heat, which

20 will impart a baked taste. Caramelization may impart flavor, mouthfeel, texture, and other properties to foods. Thus, the roasting process and carbonization and caramelization reactions may also contribute to the sensation or condition of satiety. The invention also comprises instructions for consuming a grain product that has been roasted to impart

carmelization to the product for the purpose of appetite suppression and/or weight reduction.

It will be appreciated that the mechanism by which POSTUM® suppresses appetite, and hence reduces food consumption, is unnecessary to practice the inventive method.

Other variations or embodiments of the invention will also be apparent to one of ordinary skill in the art from the above description. As one example, instructions may indicate intermittent consumption of the beverage, food, or oral dosage form to assist an individual in maintaining a desired weight, and may also provide relief of constipation experienced by individuals on a weight reduction regimen. As another example, instructions may indicate consumption of the beverage or food as part of a health and/or diet regimen. Thus, the forgoing embodiments are not to be construed as limiting the scope of this invention.

What is claimed is: